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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/750,545 | 12/31/2003 | Jon D. Kaiser | 069738-0011 | 5578 |

41552 7590 02/12/2007

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| EXAMINER | |
|---|---|
| ARNOLD, ERNST V | |
| **ART UNIT** | **PAPER NUMBER** |
| 1616 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 02/12/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/750,545 | KAISER, JON D. | |
| | Examiner | Art Unit | |
| | Ernst V. Arnold | 1616 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *20 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-66* is/are pending in the application.

4a) Of the above claim(s) *28-66* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Claims 1-66 are pending.

Applicant's remarks filed on 9/20/06 have been carefully considered by the Examiner and are not persuasive. This action is FINAL. Claims 1-27 are under examination.

Comment: Please note that proper Markush language "selected from the group consisting of" should be used in claims 2, 4, 6, 13, and 15.

**Withdrawn rejections:**

Claims 1, 4-6 and 8-11 were rejected under 35 U.S.C. 102(b) as being anticipated by Gorsek (US 6,103,756). Applicant asserted that the Gorsek does not describe a nutrient composition containing four high potency antioxidants and that the instant application excludes 3 of the alleged high potency antioxidants pointed to in Gorsek. Applicant directs the Examiner's attention to the specification at paragraph [0042] where it describes: "Bioflavinoid complex, or vitamin P, includes the substances rutin, citrin, hesperidin and quercitin.". While the art teaches that boiflavonoids are sometimes referred to as "vitamin P" but they are not vitamins in the strictest sense of the word, Applicant can be their own lexicographer. Here, Applicant defines bioflavonoids as vitamin P. The Examiner withdraws the rejection over Gorsek.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-27 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over Kosbab (US 2001/0031744).

Kosbab teaches therapeutic compositions and provides an exemplary formulation dosage comprising at least one vitamin antioxidant, at least one mineral antioxidant and at least three high potency antioxidants: 1000 mg vitamin C; 714 mg vitamin E; 4.88 mg vitamin B6; 5000 IU vitamin A; 30 mg zinc; 20 mg alpha lipoic acid; 200 mg N-acetyl-cysteine; 50 mg acetyl L-carnitine (Page 21, Table 4). Kosbab teaches preferred dosage ranges for exemplary formula components: 10-5000 mg vitamin C; 5-800 mg vitamin E; 0.001-200 mg vitamin B6; 1000-25000 IU vitamin A; 1-2000 mg quercitin (bioflavonoids); 10-3000 mg zinc; 0.001-50 mg selenium; 5-1000 mg alpha lipoic acid; 5-3000 mg N-acetyl-cysteine; and 10-3000 mg acetyl L-carnitine (Page 21, Table 3). Kosbab does not add fillers, binders or lubricants so the composition is substantially pure. The weight range of high potency antioxidants that can be in the composition of Kosbab encompasses the amount as disclosed in the instant specification in Figure 1:

| Three colored capsules contain: | |
|---|---|
| Alpha Lipoic Acid | 200 mg |
| Acetyl L-Carnitine | 500 mg |
| N-Acetyl Cysteine | 600 mg |

**Figure 1**

1. Kosbab does not expressly disclose a nutrient composition comprising highly saturable amounts of at least three high potency antioxidants.

2. Kosbab does not expressly disclose a nutrient composition with at least three vitamin antioxidants, at least two mineral antioxidants and at least 3 high potency antioxidants.

3. Kosbab does not expressly disclose a nutrient composition for augmenting immune strength or physiological detoxification comprising an optimal combination of a substantially pure and an effective amount of vitamin C, bioflavonoid complex, vitamin E, zinc, selenium, alpha lipoic acid, acetyl L-carnitine and N-acetyl-cysteine.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the composition of Kosbab to produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Kosbab provides the preferred dosage ranges of formula components such that one of ordinary skill in the art could reduce to practice the instant invention by: 1) adding highly saturable amounts of at least 3 high potency antioxidants; 2) adding selenium as another mineral antioxidant and produce a formula comprising 3) vitamin C, bioflavonoid complex, vitamin E, zinc, selenium, alpha lipoic acid, acetyl L-carnitine and N-acetyl-cysteine.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the combined teachings of the cited references.

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, (for augmenting immune strength or physiological detoxification) however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

**Response to arguments:**

Applicant asserted that Kosbab fails to suggest a formulation containing highly saturable amounts of at least three high potency antioxidants and that the Examiner failed to show or articulate why one of ordinary skill in the art would be motivated to include (1) at least three high potency antioxidants and (2) include them in highly saturable amounts. Applicant asserted that Table 3 of Kosbab merely provides a listing of all components having very general ranges and lacks specificity and that the Examiner has used hindsight reconstruction focusing on the solution to the problem after reading Applicant's specification. The Examiner cannot agree. Kosbab teaches one of ordinary skill in the art the upper limits of how much of each ingredient to

add to the composition. Table 4 brings the 3 high potency antioxidants together in one exemplary formulation and Kosbab teaches in Table 3 the possible upper limits of each of these components which would read on Applicant's definition of high potency antioxidant. Thus, Kosbab teaches higher amounts of each of the high potency antioxidants as well as the other components. It remains the Examiner's position that Kosbab provides enough guidance for one of ordinary skill in the art to produce the instant invention.

***Claim Rejections - 35 USC § 103***

Claims 1-27 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over Gorsek (US 6,103,756) in view of Ames et al. (US 5,916,912) and Kosbab (US 2001/0031744).

The references of Gorsek and Kosbab are discussed above and those discussions are hereby incorporated by reference.

Gorsek teaches a serving size contained in 6 capsules that comprising: 150 mg alpha lipoic acid; 200 mg N-acetyl-cysteine; 10 mg glutathione; 1.5 g vitamin C; 500 IU vitamin E; 17,500 IU vitamin A; 800 mcg folic acid; 50 mg vitamin B6; 25 mg zinc; 200 mcg selenium and 450 mg of bioflavonoids from 3 sources. Gorsek teaches that one skilled in the art can easily modify or change the formulation within the specific description to provide a unique product (Column 2, lines 25-27). The Examiner interprets this to mean that one of ordinary skill in the art can add or subtract to the amount of each ingredient.

1. Gorsek does not expressly disclose a nutrient composition comprising acetyl L-carnitine.

2. Gorsek does not expressly disclose a nutrient composition for augmenting immune strength or physiological detoxification comprising an optimal combination of a substantially pure and an effective amount of vitamin C, bioflavonoid complex, vitamin E, zinc, selenium, alpha lipoic acid, acetyl L-carnitine and N-acetyl-cysteine. The reference of Gorsek is lacking acetyl L-carnitine.

Ames et al. teaches a formulation comprising at least one antioxidant (250 mg of: glutathione, N-acetyl cysteine and lipoic acid) and 250 mg of acetyl L-carnitine (Claims 1, 6, 8 and 10, for example). Ames et al. disclose the beneficial effect of administering the combination on restoring mitochondrial function in older animals (Column 1, lines 40-47).

Kosbab teaches the amount of antioxidants to use in the composition (Page 21, Table 3).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the composition of Gorsek with a highly saturable amount of acetyl L-carnitine, as suggested by Ames et al. and Kosbab, for the purpose of reversing the indicia of aging, as taught by Ames et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because restoration of youth is a desirable health benefit as well as an excellent marketing feature to the composition.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the

invention and the claimed invention as a whole have been fairly disclosed or suggested by the combined teachings of the cited references.

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, (for augmenting immune strength or physiological detoxification) however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

**Response to arguments:**

Applicant asserted that the cited references are nothing more than mere identification of elements of the claimed invention. Applicant asserted that Ames et al. is directed to using two antioxidants for enhancing mitochondrial function and that there is nothing apparent in Ames et al. that would suggest to one of ordinary skill in the art to bring together at least three high potency antioxidants. The Examiner cannot agree. Gorsek teaches that one skilled in the art can easily modify or change the formulation within the specific description to provide a unique product. Thus, Gorsek provides the motivation to one of ordinary skill in the art to add or change the formulation. Kosbab teaches the amount of ingredients and Ames et al. teaches the benefits of adding acetyl L-carnitine.

Applicant asserted that Ames et al. teaches that two antioxidants achieve the intended purposes and fails to teach three high potency antioxidants. The Examiner cannot agree. Ames et

al. teach the antioxidant comprises at least one of glutathione, N-acetyl cysteine and lipoic acid (Claim 3). Thus, Ames et al. teach that all three high potency antioxidants can be present.

***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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